REMARKS

Claims 1, 2 and 4 – 13 are currently pending. In the next-to-last Office Action, the Examiner only objected to Claims 4 and 5 as being dependent upon a cancelled claim (Claim 3), and he indicated that the correction of this discrepancy would put the entire case in condition for allowance. Applicants responded with an appropriate amendment, shifting the dependency of Claims 4 and 5 to Claim 1 consistent with the Examiner's suggestion. Applicants reasonably expected this to lead to issuance of a Notice of Allowance. Instead, Applicants received yet another action on the merits where different claims are rejected based on new art. This is very puzzling and frustrating. It is hoped that this case will once and for all be favorably resolved based on this response.

In the most recent Office Action, the Examiner shifts his position to a new reference, contending now that Claims 1, 4 – 8, 12, and 13 would have been obvious from PCT application WO 01/72284 to Schwarz. On the other hand, Claims 2 and 9 – 11 are said to be only objected to as being dependent upon a rejected base claim. It is Applicants' interpretation of this latest action that the subject matter of Claims 2 and 9 – 11 is considered to patentably distinguish over the prior art. Accordingly, Claims 2 and 9 have been rewritten in independent form in accordance with Applicants' interpretation of the Examiner's position in regard to these claims. In view of this amendment, it is submitted all the objections to Claims 2 and 9 have been overcome, and that the same should be withdrawn. And, since Claims 10 and 11 depend from what is now independent Claim 9, all objections to these claims have also been overcome and should be withdrawn. As a result, Claims 2 and 9-11 should be allowed.

Turning now to the new rejection of Claims 1, 4-8, 12, and 13 based on Schwarz. Applicants respectfully submit that these rejections are not well taken, and should be withdrawn. Among other things, Schwarz fails to suggest an intermediate layer containing cellulosic derivatives enclosing a core containing antibiotic particles. In fact, by suggesting only the mixing of cellulosic material with the active ingredient (rather than "coating" it), Schwarz actually would have led a person of skill away from the micropellet structure claimed by Applicants.

As amended herein, Claim 1 recites a pharmaceutical composition comprising a plurality of taste masking micropellets. Each micropellet is composed of at least three separate layers or parts. First is antibiotic particles. Generally, the antibiotic is a bitter- tasting substance, such as clarithromycin. Second is an inner layer coating the antibiotic particles. The inner layer comprises at least one cellulose polymer selected from the group consisting of hydroxypropylmethyl cellulose, hydroxypropyl cellulose, methyl cellulose, ethyl cellulose, carboxymethylethyl cellulose, sodium carboxymethyl cellulose, ethylcarboxyethyl cellulose, and combinations thereof. Third is an outer coating on the inner layer. The outer coating comprises an enteric coating polymer. As noted on page 3 of the specification, a pharmaceutical composition of micropellets layered in this manner has been found to provide effective masking of the bitter taste of the antibiotic active ingredient while still allowing for fast dissolution and improved bioavailability of the active ingredient once it reaches the absorption region of the intestine.

This structure is neither disclosed nor suggested by Schwarz. The pellets described by Schwarz have only two layers: a core and an outer enteric coating. *See*, e.g., Schwarz, page 1, lines 23 – 33 and page 7, lines 8 – 17. Schwarz says nothing about an inner coating layer disposed between a center region of antibiotic particles and an outer enteric coating layer as called for in Claim 1. This novel structure is mentioned nowhere in Schwarz, or in any of the other cited references.

Granted, Schwarz does mention the use of cellulose derivatives such as hydroxypropylmethyl cellulose, but he plainly teaches that any such additives are "premixed" with the active ingredient prior to granulation. *See*, page 6, lines 3 – 7 and Examples 1 and 2. Thus, following Schwarz, a person of skill might be led to incorporate a cellulose derivative into a core. But nothing in Schwarz would lead one to configure micropellets with a separate coating or layer containing cellulose derivatives intermediate a center containing antibiotic particles and an outer enteric layer.

Given these distinctions, Schwarz cannot fairly be said to disclose or suggest the subject matter of Claim 1 (or in any of its dependent Claims 4 – 8, 12, and 13). By specifically teaching the premixing of any cellulose derivatives with the active ingredient, Schwarz in effect teaches away from Claim 1 where cellulose derivatives are specified in an intermediate

layer between an interior center containing antibiotic particles and an outer enteric coating layer, not as part of the antibiotic material itself.[1]

In light of the foregoing, Applicants urge the Examiner to reconsider the application, to withdraw all rejections and objections, and to issue a Notice of Allowance at the earliest possible convenience.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,
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[1] Of course, this does not mean the antibiotic particles in the center could not contain some cellulose derivatives. But it does mean there must be a second or intermediate layer containing cellulose derivates, among other things, between antibiotic particles in the center and an outer enteric coating layer. Schwarz does not disclose or suggest inclusion of cellulosic derivatives in any such separate intermediate layer disposed between a center containing antibiotic particles and an outer enteric coating layer.